SEP - 7 2001

510(k) SUMMARY

K011828

Submitter:	Cynsoure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	June 11, 2001
Device Trade Name:	Acclaim Dermatology Laser
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48
Equivalent Device:	Cynosure PhotoGenica DL Laser and Altus Medical Aesthetic Nd:YAG Laser.
Device Description:	The Acclaim is a pulsed solid state laser, emitting at the near intra-red wavelength of 1064nm. Laser activation is both by finger switch and footswitch. Overall weight of the laser is 285lbs, and the size is 44"x19"x24" (HxWxD). Electrical requirement is 110 VAC or 220 VAC, 20A, 50-60 Hz, single phase.
Intended Use:	The Acclaim Dermatology Laser is indicated for benign vascular lesions and hair removal.
Comparison:	The Acclaim Dermatology Laser has the same indication for uses, the same principle of operation, the same wavelength and pulse energy range as the predicate devices.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The Acclaim Dermatology Laser is another safe and effective device for dermatologic applications.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. George Cho
Senior Vice President
Medical Technology
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K011828
Trade/Device Name: Cynosure Acclaim Dermatology Laser
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 11, 2001
Received: June 12, 2001

Dear Mr. Cho:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

501(k) Number (if known): K011828

Device Name: Cynosure Acclaim Dermatology Laser

Indications For Use:

The Cynosure Acclaim Dermatology Laser is indicated for the treatment of benign cutaneous vascular lesions and hair removal.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011828

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)